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UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO

IN RE: HEPARIN PRODUCTS LIABILITY LITIGATION))))	MDL Docket No. 1953 CHIEF JUDGE JAMES G. CARR CASE NO. 1:08-hc-60000
JOYCE ANN WILLIAMS, Individually	•	
and as Administratrix and Personal	•	MDL DOCKET NO. 1953
Representative of the ESTATE OF	•	
FREDDIE JAMES WILLIAMS, SR.,	:	AMENDED
DECEASED	:	COMPLAINT FOR:
3840 EE Highway	:	
Neelyville, MO 63954	:	(1) Strict Liability;
•	:	(2) Negligence;
VS.	:	(3) Breach of Warranty;
	:	(4) Wrongful Death;
TYCO HEALTHCARE GROUP, L.P.	:	(5) Survival Act;
15 Hampshire Street	:	(6) Fraud
Mansfield, MA 02048	:	
AND	:	
COVIDIEN INC.	:	CIVIL CASE NO. 1:08-600034
15 Hampshire Street	:	
Mansfield, MA 02048	:	
AND	:	
SCIENTIFIC PROTEIN	:	
LABORATORIES, LLC	:	
700 East Main Street	:	
Waunakee, WI 53597	:	
AND	:	

CHANGZHOU SPL COMPANY, LTD.

a/k/a Kaipu Biochemical Co.

3 Changhong West Road

Wujing, Changzhou City

Jiangsu Province, China

AND

TECH POOL BIO-PHARMA CO., LTD.

89 Gaopu Road

Gaotang Scien-Tech Industrial Park

Tianhe, Guangzhou

Peoples Republic of China 510520

AMENDED COMPLAINT

AND NOW, comes Plaintiff, Joyce Ann Williams, Individually and as Administratrix and Personal Representative of the Estate of Freddie James Williams, Sr., Deceased (hereinafter "Plaintiff"), by and through the undersigned counsel and complains of Defendants, Tyco HealthCare Group, L.P., Covidien Inc., (collectively "Tyco Healthcare"), Scientific Protein Laboratories, LLC ("SPL"), Changzhou SPL Company, Ltd. a/k/a Kaipu Biochemical Co. ("CZSPL"), and Tech Pool Bio-Pharma Co., Ltd. ("Tech Pool") (collectively "Defendants") as follows:

INTRODUCTION

1. This is a Wrongful Death and Survival action related to the death of Freddie James Williams, Sr., who was administered recalled Heparin imported from China.

JURISDICTION

2. This Court has diversity of citizenship jurisdiction pursuant to Title 28 U.S.C. §1332. Plaintiff is a resident of Missouri and all Defendants conduct regular, systemic, continuous and substantial business, or are headquartered, or are incorporated in the Commonwealth of Massachusetts.

VENUE

3. Plaintiff is a resident of Missouri and Defendant, Tyco Healthcare is headquartered in Massachusetts.

PARTIES

- 4. Plaintiff, Joyce Ann Williams, is an adult individual residing at 3840 EE Highway, Neelyville, MO 63954.
- 5. Plaintiff, Joyce Ann Williams, is acting as the Administratrix and Personal Representative of the Estate of Freddie James Williams, Sr., Deceased ("Estate").
- 6. Prior to his death, Freddie James Williams, Sr. ("Decedent"), was an adult individual residing at 3840 EE Highway, Neelyville, MO 63954.
 - 7. Decedent was born on August 10, 1941, and died on March 28, 2008.
 - 8. At the time of his death Decedent was married to Plaintiff.
- 9. Plaintiff brings this action Individually and as Administratrix and Personal Representative of the Estate and on behalf of the Estate and Decedent's surviving wrongful death beneficiaries ("Beneficiaries"), who are as follows:
 - (a) Joyce Ann Williams Spouse, Married on June 19, 1965;
- (b) Charlotte Ballard, natural child of Freddie James Williams, Sr. and Joyce Ann Williams, 2035 North Travis, Springfield, MO 65803, DOB: 1-29-66;
- (c) Freddie Williams, Jr., natural child of Freddie James Williams, Sr. and Joyce Ann Williams, 826 Old 67 Highway, Neelyville, MO 63954, DOB: 6-16-67;
- (d) Mary Williams, natural child of Freddie James Williams, Sr. and Joyce Ann Williams, 3840 EE Highway, Neelyville, MO 63954, DOB: 6-5-68;

- (e) Tabitha Williams, natural child of Freddie James Williams, Sr. and Joyce Ann Williams, 3870 EE Highway, Neelyville, MO 63954, DOB: 6-18-70;
- (f) Irish Williams, natural child of Freddie James Williams, Sr. and Joyce Ann Williams, 145 Center Street, Neelyville, MO 63954, DOB: 10/29/71;
- (g) Mark Williams, natural child of Freddie James Williams, Sr. and Joyce Ann Williams, 145 Center Street, Neelyville, MO 63954, DOB: 3-16-77;
- (h) Tony Williams, natural child of Freddie James Williams, Sr. and Joyce Ann Williams, 2464 County Road 309, Poplar Bluff, MO 63901, DOB: 6-2-78;
- (i) Renea Smith, natural child of Freddie James Williams, Sr. and Joyce Ann Williams, 131 Hampton Court, Poplar Bluff, MO 63901, DOB: 6-2-78;
- (j) Jarrel Williams, natural child of Freddie James Williams, Sr. and Joyce Ann Williams, 925 Oakwood Drive, Poplar Bluff, MO 63901, DOB: 1-28-80;
- (k) Cody Williams, natural child of Freddie James Williams Sr. and Joyce Ann Williams, 147 Center Street, Neelyville, MO 63954, DOB: 7-17-81;
- (k) Gary Williams, natural child of Freddie James Williams, Sr., 735 Mill Street, Poplar Bluff, MO 63901, DOB: 9-9-66.
- 10. Defendant, Tyco Healthcare Group, LP, upon information and belief, has a headquarter office or usual place of business at 15 Hampshire Street, Mansfield, MA 02048.
- 11. Covidien Inc. is the general partner to Tyco Healthcare Group, LP, and upon information and belief, is a Massachusetts corporation, with a headquarter office or usual place of business at 15 Hampshire Street, Mansfield, MA 02048.

- 12. Defendant, Tyco Healthcare, directly and through its agents, servants, employees and subsidiaries, at all times mentioned herein and material hereto, conducted regular, systematic, continuous and substantial business within the Commonwealth of Massachusetts.
- 13. Defendant, Tyco Healthcare, directly and through its agents, servants, employees and subsidiaries, at all times mentioned herein and material hereto, was in the business of manufacturing, selling and distributing Monoject Prefill TM 100 U/ML Heparin Lock Flush 5 ML Syringes ("Syringes").
- 14. Defendant, SPL, upon information and belief, is a Delaware Limited Liability Company, with a headquarter office or usual place of business at 2711 Centerville Road, Suite 400, Wilmington, DE 19808.
- 15. Defendant, SPL, directly and through its agents, servants, employees and subsidiaries, at all times mentioned herein and material hereto, conducted regular, systematic, continuous and substantial business within the Commonwealth of Massachusetts.
- 16. Defendant, SPL, directly and through its agents, servants, employees and subsidiaries, at all times mentioned herein and material hereto, was in the business of manufacturing, selling and distributing Heparin and Heparin products, including the Active Pharmaceutical Ingredient ("API") for Heparin which was supplied to the Defendants for use in the Syringes.
- 17. Defendant, CZSPL, is a joint venture between Defendants SPL and Tech Pool, which is a Heparin manufacturing and processing facility ("Plant") located at 3 Chang Hong West Road Wujing, Changzhou City, Jiangsu Province, China.

- 18. Defendant, CZSPL, directly and through its agents, servants, employees and subsidiaries, at all times mentioned herein and material hereto, conducted regular, systematic, continuous and substantial business within the Commonwealth of Massachusetts.
- 19. Defendant, CZSPL, directly and through its agents, servants, employees and subsidiaries, at all times mentioned herein and material hereto, was in the business of manufacturing, selling and distributing Heparin and Heparin products, including the API for Heparin which was supplied to the Defendants for use in the Syringes.
- 20. Defendant, Tech Pool, upon information and belief, is a foreign corporation, with a headquarter office or usual place of business at 89 Gaopu Road, Gaotang Scien-Tech Industrial Park, Tianhe, Guangzhou, Peoples Republic of China 510520.
- 21. Defendant, Tech Pool, directly and through its agents, servants, employees and subsidiaries, at all times mentioned herein and material hereto, conducted regular, systematic, continuous and substantial business within the Commonwealth of Massachusetts.
- 22. Defendant, Tech Pool, directly and through its agents, servants, employees and subsidiaries, at all times mentioned herein and material hereto, was in the business of manufacturing, selling and distributing Heparin and Heparin products, including the API for Heparin which was supplied to the Defendants for use in the Syringes.

FACTUAL ALLEGATIONS

- 23. Heparin is a prescription drug in a class of medications called anticoagulants, also known as blood thinners.
- 24. Heparin products, including the API for Heparin, manufactured at the Plant, were supplied to Defendants for use in the Syringes.
- 25. Defendants, SPL, CZSPL and Tech Pool represent that the Plant is designed and constructed in strict accordance with Good Manufacturing Practice ("GMP") standards, has rationale layout, distinct classifications, proper production process which is free from intercross between personnel flow and material flow, which guarantees the product quality.
- 26. Defendants, SPL, CZSPL and Tech Pool further represent the Plant is validated strictly according to the GMP requirements annually, which enhance the assurance of the product quality.
- 27. Defendants, SPL, CZSPL and Tech Pool further represent managing staff conduct and production control in strict compliance with the GMP requirements, which includes a post-duty system and total control of key processes with statistical analysis. They also have the responsibilities of establishing a perfect filing system that records process regulations, standard operating procedures and post-duties.
- 28. Defendants, SPL, CZSPL and Tech Pool represent that the Plant is a new, state of the art, fully validated GMP compliant Heparin API manufacturing facility.
- 29. Defendants, SPL, CZSPL and Tech Pool represent Heparin produced at the Plant was approved by the Food and Drug Administration ("FDA") in 2004 under the U.S. MDA for import and use in the United States.

- 30. Defendants, SPL, CZSPL and Tech Pool represent that the Plant is operated strictly in accordance with FDA's GMP requirements.
- 31. Defendants, SPL, CZSPL and Tech Pool represent that the Plant is regularly inspected by multiple regulatory agencies such as the FDA and United States Department of Agriculture ("USDA") and is subject to many annual customer audits.
- 32. Defendants, SPL, CZSPL and Tech Pool represent that it rigorously applies the same work processes, documentation requirements and QA/QC regimen at both the Plant, as well as, its facility in Wisconsin.
 - 33. Heparin, is a prescription injectible blood anti-coagulant.
 - 34. The API for Heparin is derived from pig intestines.
- 35. Mucus membranes from pig intestines are cooked, eventually producing a dry substance known as Crude Heparin.
- 36. Crude Heparin is refined and processed and eventually used in the manufacture of Heparin anti-coagulants and Heparin Lock Flushes.
- 37. During 2007, there was a shortage of pigs in China due to an outbreak of Blue Ear Pig Disease.
- 38. The pig shortage correspondingly drove the price of pig intestines up during 2007.
- 39. Defendants, SPL, CZSPL and Tech Pool began purchasing Crude Heparin from small non-regulated suppliers in China.

- 40. Due to the pig shortage, the Crude Heparin obtained and used by Defendants, SPL, CZSPL and Tech Pool was adulterated and counterfeited by over sulfated Chondroitin Sulfate, which is derived from animal cartilage.
- 41. Chondroitin Sulfate is an over the counter dietary supplement commonly used to assist with joint pain.
 - 42. Over sulfated Chondroitin Sulfate is known to mimic the API of Heparin.
- 43. The adulterated Heparin API was used by major U.S. pharmaceutical manufacturers and distributors, such as Baxter, B. Braun and Tyco, in their Heparin products which were distributed at least during the fourth quarter of 2007 and the first quarter of 2008.
- 44. On January 7, 2008, the Missouri Department of Health and Senior Services notified the Center for Disease Control ("CDC") of an outbreak of acute allergic type reactions among both adult and pediatric hemodialysis patients since November 19, 2007.
- 45. Between November 19, 2007 and January 15, 2008, eight (8) episodes of allergic type reactions among both pediatric and adult patients in Missouri were reported.
- 46. The most common sequel of allergic symptoms consisted of difficulty breathing, nausea, vomiting, excessive sweating and rapidly falling blood pressure.
- 47. However, the entire sequel of reported symptoms is known to include stomach pain or discomfort, nausea, vomiting, diarrhea, decreased or low blood pressure, chest pain, fast heart rate, dizziness, fainting, unresponsiveness, shortness of breath, the feeling of a strong or rapid heart beat, drug ineffectiveness, burning sensation, redness or paleness of skin, abnormal sensation of the skin, mouth or lips flushing, increased

sweating, decreased skin sensitivity, headache, feeling unwell, restlessness, watery eyes, throat swelling, thirst, bleeding tendencies and difficulty opening the mouth.

- 48. The CDC began immediately investigating hemodialysis centers throughout the country.
- 49. On January 9, 2008, the CDC alerted the FDA and began cooperating with the FDA on this investigation.
- 50. On January 17, 2008, Baxter began recalling Heparin products manufactured with Heparin API from the SPL, CZSPL and Tech Pool Plants. The Heparin recalled by Baxter was manufactured with API supplied by SPL, CZSPL and Tech Pool manufactured at the Plant.
 - 51. On February 11, 2008, Baxter halted its Heparin manufacturing.
- 52. Between February 20, 2008 and February 26, 2008, the FDA inspected the Plant.
- 53. The multiple violations noted by the FDA include, but are not limited to, the following:
 - (a) Manufacturing and distributing adulterated Heparin;
- (b) Failing to comply with current good manufacturing practices in the manufacture of Heparin;
 - (c) Violating the Federal Food, Drug and Cosmetic Act;
- (d) Failing to have critical processing steps for the repeated and efficient removal of impurities from Heparin;
 - (e) Failing to establish an impurities profile;
 - (f) Failing to test adequately to detect impurities in API;

- (g) Failing to evaluate for degradants during stability program testing;
- (h) Failure to perform test method verifications;
- (i) Failing to conduct routine tests for residue;
- (j) Failing to investigate the cause of failed lots;
- (k) Failing to keep records showing the source of vendors;
- (1) Manufacturing with Heparin Crude Lots from unacceptable vendors;
- (m) Manufacturing with scraps of uncleaned tanks with unidentified materials adhering to the inside;
 - (n) Failing to use validated tank cleaning methods;
 - (o) Failing to obtain appropriate raw material inventory records;
 - (p) Inadequate control of the material flow in the processing area;
- (q) Ineffective system for evaluating suppliers of crude Heparin materials;
- (r) Failing to take corrective action after determining the crude material supplies were unacceptable;
- (s) Failing to establish appropriate specification for incoming crude material;
 - (t) Failing to monitor and scrutinize crude material suppliers;
 - (u) Failing to maintain an adequate vendor qualification program;
- (v) Failing to have all crude material proved by the quality unit before use;
 - (w) Violating the ICH;

- (x) Failing to maintain written procedures for the cleaning of equipment; and
- (y) Failing to maintain quality control to assure the API meets its established specifications for identity, quality and purity.
- 54. The FDA has and continues to refuse admission into the United States of America Heparin API originating from the Plant.
- 55. On February 28, 2008, Baxter recalled its Heparin Lock Flush Syringes. The Heparin recalled by Baxter was manufactured with API supplied by SPL, CZSPL and Tech Pool manufactured at the Plant.
- 56. On March 20, 2008, American Health Packaging of Valley Forge, Pennsylvania recalled Heparin vials manufactured by Baxter that were placed into American Health Packaging individually labeled bags for use in pharmacy automation equipment. The Heparin recalled by Baxter was manufactured with API supplied by SPL, CZSPL and Tech Pool and manufactured at the Plant.
- 57. On March 21, 2008, B. Braun issued a recall of Heparin products. The Heparin recalled by B. Braun was manufactured with API supplied by SPL, CZSPL and Tech Pool and manufactured at the Plant.
- 58. On March 28, 2008, Tyco Healthcare recalled Heparin Lock Flush Syringes, including Syringes from Lot Number 8010174.
- 59. Between at least November of 2007 and March 28, 2008, Decedent was administered Heparin Lock Flushes.
- 60. Decedent was specifically administered Heparin Lock Flush Syringes from Lot Number 8010174, as well as, other adulterated Heparin.

- 61. Shortly after administration of the adulterated Heparin, Decedent exhibited allergic reaction symptoms including difficulty breathing, nausea, vomiting, excessive sweating, rapidly falling blood pressure and convulsions.
- 62. On March 28, 2008, Decedent died as a direct and proximate result of chronic and acute exposure to the adulterated Heparin.

COUNT I – STRICT LIABILITY PLAINTIFF VS. DEFENDANTS

- 63. Plaintiff hereby incorporates all matter stated elsewhere in this pleading as if fully set forth herein at length.
 - 64. Defendants manufactured and distributed adulterated Heparin to Decedent.
- 65. The adulterated Heparin manufactured and distributed by Defendants was unreasonably dangerous and defective.
- 66. As a direct and proximate result of Defendants' manufacturing and distribution of adulterated Heparin, Decedent was caused to experience multiple acute and chronic adverse reactions thereby resulting in serious and permanent injuries and subsequent death.
- 67. As a direct and proximate result of the injuries and death, Decedent suffered great pain, anguish, sickness and anxiety.
- 68. As a direct and proximate result of the injuries and death, Decedent suffered emotional injuries, mental anguish, humiliation, loss of life's pleasures, loss of hedonic pleasures and the inability to attend to social and work obligations.
- 69. As a direct and proximate result of the injuries and death, Decedent has undergone a great loss of earnings and earning capacity and by reason of death, has sustained a great loss of all future earnings and earning capacity.

70. As a direct and proximate result of the injuries, Decedent has incurred medical and rehabilitative expenses that are hereby claimed in this action.

<u>COUNT II – NEGLIGENCE</u> <u>PLAINTIFF VS. DEFENDANTS</u>

- 71. Plaintiff hereby incorporates all matter stated elsewhere in this pleading as if fully set forth herein at length.
- 72. Defendants negligently, carelessly and recklessly manufactured and distributed the adulterated Heparin.
- 73. The negligence, carelessness and recklessness of Defendants includes, but is not limited to:
 - (a) Manufacturing and distributing adulterated Heparin;
- (b) Failing to comply with current GMP in the manufacture of Heparin;
 - (c) Violating the Federal Food, Drug and Cosmetic Act;
- (d) Failing to have critical processing steps for the repeated and efficient removal of impurities from Heparin;
 - (e) Failing to establish an impurities profile;
 - (f) Failing to test adequately to detect impurities in API;
 - (g) Failing to evaluate for degradants during stability program testing;
 - (h) Failure to perform test method verifications;
 - (i) Failing to conduct routine tests for residue;
 - (j) Failing to investigate the cause of failed lots;
 - (k) Failing to keep records showing the source of vendors;

- (l) Manufacturing with Heparin Crude Lots from unacceptable vendors;
- (m) Manufacturing with scraps of uncleaned tanks with unidentified materials adhering to the inside;
 - (n) Failing to use validated tank cleaning methods;
 - (o) Failing to obtain appropriate raw material inventory records;
 - (p) Inadequate control of the material flow in the processing area;
- (q) Ineffective system for evaluating suppliers of crude Heparin materials;
- (r) Failing to take corrective action after determining the crude material supplies were unacceptable;
- (s) Failing to establish appropriate specification for incoming crude material;
 - (t) Failing to monitor and scrutinize crude material suppliers;
 - (u) Failing to maintain an adequate vendor qualification program;
- (v) Failing to have all crude material proved by the quality unit before use;
 - (w) Violating the ICH;
- (x) Failing to maintain written procedures for the cleaning of equipment;
- (y) Failing to maintain quality control to assure the API meets its established specifications for identity, quality and purity;
 - (z) Failing to maintain and implement adequate quality control;

- (aa) Failing to take action to recall the adulterated Heparin sooner;
- (bb) Substituting Crude Heparin with over sulfated Chondroitin Sulfate;
- (cc) Choosing not to take reasonable care in the manufacturing and distribution of Heparin;
 - (dd) Choosing not to use reasonable care in testing the Heparin;
 - (ee) Choosing not to use due care under the circumstances; and
 - (ff) Negligence at law.
- 74. As a direct and proximate result of the negligence, carelessness and recklessness of Defendants, Decedent was caused to experience multiple acute and chronic adverse reactions thereby resulting in serious and permanent injuries and subsequent death.
- 75. As a direct and proximate result of the injuries and death, Decedent suffered great pain, anguish, sickness and agony.
- 76. As a direct and proximate result of the injuries and death, Decedent suffered emotional injuries, mental anguish, humiliation, loss of life's pleasures, loss of hedonic pleasures and the inability to attend to social and work obligations.
- 77. As a direct and proximate result of the injuries, Decedent has undergone a great loss of earnings and earning capacity and by reason of the death has sustained a great loss of all future earnings and earning capacity.
- 78. As a direct and proximate result of the injuries, Decedent has incurred medical, rehabilitative and other expenses which are hereby claimed in this action.

COUNT III – BREACH OF WARRANTY PLAINTIFFS VS. DEFENDANTS

- 79. Plaintiff hereby incorporates all matter stated elsewhere in this pleading as if fully set forth herein at length.
- 80. Defendants breached their warranties, both expressed and implied, that the adulterated Heparin was safe and proper for its intended and foreseeable use and was manufactured such that it would be safe for its intended use.
- 81. Defendants breached their warranties, both expressed and implied, by manufacturing and distributing the adulterated Heparin such that it was unsafe, defective and of non-merchantable quality and not reasonably safe for the uses for which it was intended and for which was reasonably foreseeable.
- 82. As a direct and proximate result of Defendants breach of its express and implied warranties, Decedent was caused to experience multiple acute and chronic adverse reactions thereby resulting in serious and permanent injuries and subsequent death.
- 83. As a direct and proximate result of the injuries and death, Decedent suffered great pain, anguish, sickness and agony.
- 84. As a direct and proximate result of the injuries and death, Decedent suffered emotional injuries, mental anguish, humiliation, loss of life's pleasures, loss of hedonic pleasures and the inability to attend to social and work obligations.
- 85. As a direct and proximate result of the injuries, Decedent has undergone a great loss of earnings and earning capacity and by reason of the death, Decedent has sustained a great loss of all future earnings and earning capacity.

86. As a direct and proximate result of the injuries, Decedent has incurred medical, rehabilitative and other expenses which are hereby claimed in this action.

COUNT IV – WRONGFUL DEATH PLAINTIFFS VS. DEFENDANTS

- 87. Plaintiff hereby incorporates all matter stated elsewhere in this pleading as if fully set forth herein at length.
- 88. As a direct and proximate result of Defendants negligence, negligence per se, carelessness, recklessness and strict liability, Decedent was caused to experience multiple acute and chronic adverse reactions thereby resulting in serious and permanent injuries and subsequent death.
- 89. Plaintiff brings this action on behalf of Decedent's beneficiaries pursuant to the applicable Wrongful Death Act and claims all damages recoverable under the applicable Wrongful Death Act.
- 90. As a direct and proximate result of the injuries and death of Decedent, the Beneficiaries have been caused to incur and pay large and various expenses for medical treatment rendered to Decedent until the time of his death and to incur various funeral and estate administration expenses for which Plaintiff is entitled to compensation in this proceeding along with all other damages recoverable under the applicable Wrongful Death Act.
- 91. As a direct and proximate result of the injuries and death of Decedent, the Beneficiaries suffered, are suffering and will for an indefinite period of time in the future suffer damages, injuries, losses, including but not limited to, a loss of financial support and the Beneficiaries have been wrongfully deprived of the contribution they would have

received from Decedent including monies which Decedent would have provided for items such as clothing, shelter, food, medical care, education, recreation and gifts.

- 92. As a direct and proximate result of the injuries and death of Decedent, the Beneficiaries have been, continue to be, and will in the future, be wrongfully deprived of the services, society and comfort which Decedent would have provided, including work around the home and physical comforts.
- 93. As a direct and proximate result of the injuries and death of Decedent, the Beneficiaries have been, continue to be and will in the future be wrongfully deprived of the guidance, tutelage and moral upbringing which they would have received but for Decedent's wrongful death.

<u>COUNT V – SURVIVAL ACT</u> <u>PLAINTIFFS VS. DEFENDANTS</u>

- 94. Plaintiff hereby incorporates all matter stated elsewhere in this pleading as if fully set forth herein at length.
- 95. As a direct and proximate result of Defendants negligence, negligence per se, carelessness, recklessness and strict liability, Decedent suffered severe adverse reactions both chronic and acute, as well as death.
- 96. Plaintiff brings this action as Personal Representative and Administratrix of the Estate, and on behalf of the Estate, pursuant to the applicable Survival Act and claims all damages recoverable under the applicable Survival Act.
- 97. As a direct and proximate result of the injuries and death of Decedent, the Estate suffered damages and losses for the total amount Decedent would have earned between the moment of his first exposure to the adulterated Heparin and its death.

- 98. As a direct and proximate result of the injuries and death of Decedent, the Estate has suffered losses for the total net amount Decedent would have earned between the moment of his first exposure to the adulterated Heparin and the end of Decedent's work life expectancy subject to the cost and maintenance and support.
- 99. As a direct and proximate result of the injuries and death of Decedent, the Estate is entitled to be fairly and adequately compensated for the mental and physical pain, suffering and inconvenience that Decedent endured from the moment of the first exposure to the adulterated Heparin to the moment of his death on March 28, 2008.
 - 100. No recovery was made during Decedent's lifetime.

<u>COUNT VI – FRAUD</u> <u>PLAINTIFFS VS. SPL, CZSPL AND TECH POOL</u>

- 101. Plaintiff hereby incorporates all matter stated elsewhere in this pleading as if fully set forth herein at length.
- 102. All of the representation of Defendants, SPL, CZSPL and Tech Pool regarding the Plant, the Heparin manufacturing, the quality control and compliance with GMP and FDA regulations, were made knowingly, intentionally and voluntarily.
- 103. All of the representation of Defendants, SPL, CZSPL and Tech Pool regarding the Plant, the Heparin manufacturing, the quality control and compliance with GMP and FDA regulations, were false.
- 104. All of the representation of Defendants, SPL, CZSPL and Tech Pool regarding the Plant, the Heparin manufacturing, the quality control and compliance with GMP and FDA regulations, were shown to be false by reason of the FDA inspection which occurred between February 20, 2008 and February 26, 2008.

- 105. The false representation of Defendants, SPL, CZSPL and Tech Pool were relied on to Plaintiff's detriment.
- 106. As a direct and proximate result of the reliance on Defendants' misrepresentations, Decedent was caused to experience multiple acute and chronic adverse reactions thereby resulting in serious and permanent injuries and subsequent death.
- 107. As a direct and proximate result of the injuries and death, Decedent suffered great pain, anguish, sickness and agony.
- 108. As a direct and proximate result of the injuries and death, Decedent suffered emotional injuries, mental anguish, humiliation, loss of life's pleasures, loss of hedonic pleasures and the inability to attend to social and work obligations.
- 109. As a direct and proximate result of the injuries, Decedent has undergone a great loss of earnings and earning capacity and by reason of the death has sustained a great loss of all future earnings and earning capacity.
- 110. As a direct and proximate result of the injuries, Decedent has incurred medical, rehabilitative and other expenses which are hereby claimed in this action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, Joyce Ann Williams, Individually and as Administratrix of the Estate of Freddie James Williams, Sr., Deceased, respectfully pray the Court to award the following relief:

- 1. All damages recoverable under the applicable Wrongful Death Act;
- 2. All damages recoverable under the applicable Survival Act;
- 3. Punitive Damages;

- 4. Medical Expenses;
- 5. Estate Expenses;
- 6. Compensatory and Actual Damages;
- 7. Damages for Conscious Pain and Suffering;
- 8. Costs and Attorney Fees as allowed by Law; and
- 9. Such other or further relief as the Court may deem fair, appropriate and just.

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff demands a trial by jury on all questions of fact raised by the Complaint.

DATED: 6/8/09

BY:

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